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Roche

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PROCESSED

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Reduced risk for developing type 2 diabetes recommended for inclusion in Xenical's European label

Roche announced today that the European Union's Committee for Proprietary Medicinal Products (CPMP) has given a positive recommendation to extend the European label for its weight loss medication Xenical to include:

- four year data on weight loss;
- long-term safety and tolerability profile; and
- reduced risk for developing type 2 diabetes.

The decision is based on the results of the landmark XENDOS (XENical in the prevention of Diabetes in Obese Subjects) study, which showed for the first time that a weight loss medication could significantly reduce the risk of developing type 2 diabetes.1

XENDOS is the largest and longest study of a weight loss medication, treating 3304 patients for four years with Xenical plus lifestyle changes, or lifestyle changes alone. It is also the first study to assess whether treatment with a weight loss medication, Xenical, can reduce the risk of developing type 2 diabetes. The study showed that losing weight with Xenical reduced the risk of developing diabetes by 37% compared with lifestyle changes alone and by 52% in patients with impaired glucose tolerance (IGT or pre-diabetes). Compared to lifestyle changes alone, Xenical treatment produced significantly greater long-term weight loss and improvements in cardiovascular risk factors (including blood pressure and lipids). The study also confirmed that Xenical has a long-term safety profile that is unmatched in the field of weight loss.

"The CPMP's decision is an important step towards expanding the European label for Xenical, which we believe will provide physicians with an effective strategy for helping patients lose weight and thereby delaying or preventing type 2 diabetes," commented Dr. Paul Brown, Life Cycle Leader for Xenical.

The CPMP's positive opinion will now be proposed for approval by the European Commission.

Type 2 diabetes

Health experts have warned of a global epidemic of diabetes caused by a rise in overweight and obesity. There are currently 120-140 million people worldwide with type 2 diabetes, and if trends continue, this number is predicted to double in the next 25 years.2 More than 90% of all people with type 2 diabetes are overweight or obese.3 Because of the severe health and cost implications of type 2 diabetes, organisations such as the International Diabetes Federation (IDF) have called for increased efforts to prevent the development of type 2 diabetes. The IDF estimates that 314 million people worldwide, or 8.2% of the global population, have impaired glucose tolerance, a state that often precedes type 2 diabetes.4

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Excess weight

Excess weight is well recognised as the most important modifiable risk factor for the development of type 2 diabetes. A number of recent studies have shown that lifestyle changes (diet and exercise) have a dramatic effect on delaying or preventing the development of type 2 diabetes.5, 6 The XENDOS study represents an important step forward in the evolution of diabetes prevention studies through the study design and the outcomes that were measured.

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About Xenical

Xenical is the only available weight loss medication that works locally in the gut to prevent dietary fat absorption by around 30% to effectively promote weight loss. It is an effective therapy that not only helps patients lose weight, but also helps them maintain their weight loss. Xenical is well tolerated and unlike appetite suppressants, it does not act on the brain. Since it was first marketed in 1998, there have been more than 18.5 million patient treatments with Xenical worldwide. Xenical is licensed for weight management in over 140 countries around the world. For further information please go to: www.managingyourweight.com

About Xenical Weight Management Programmes

Roche has developed Xenical Weight Management Programmes (WMPs) for healthcare professionals to use with their patients. The programme aims to help patients set and reach realistic weight goals while modifying their dietary intake and behaviour in the long-term. The programmes are individually tailored to help people achieve their weight loss goals, and maintain weight loss, through healthy eating, physical activity and pharmacotherapy.

Roche provides the WMP free of charge in around 50 countries worldwide to offer additional support to patients treated with Xenical. Recent data demonstrated that patients enrolled in Xenical WMPs can significantly improve the levels of weight loss achieved and can increase their overall satisfaction and compliance with treatment.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading innovation-driven healthcare groups. Its core businesses are pharmaceuticals and diagnostics. Roche is number one in the global diagnostics market, the leading supplier of pharmaceuticals for cancer and a leader in virology and transplantation. As a supplier of products and services for the prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche employs roughly 65,000 people in 150 countries. The Group has alliances and R&D agreements with numerous partners, including majority ownership interests in Genentech and Chugai.

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- 6. Diabetes Prevention Program (DPP). NEJM, February 7, 2002. Reduction in the incidence in type 2 diabetes with lifestyle intervention or metformin.

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Media release



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Basel, 30 January 2004

Roche announces the release of the first PCR-based reagent for the detection of HPV

New PCR-based product detects all 13 high-risk Human Papillomavirus (HPV) DNA genotypes, the leading cause of cervical cancer

Roche today announced the availability of its Amplicor Human Papillomavirus (HPV) product in the US, an important milestone in the development of its women's health portfolio. The new HPV product is the first PCR-based (polymerase chain reaction) reagent for the detection of HPV and may be used by laboratories in the U.S. to develop a "home brew" assay for HPV. Roche also expects to provide a CE-marked kit in the European Union within the next few months. This product identifies all 13 high-risk genotypes of HPV. HPV is the leading cause of cervical cancer that affects more than 500,000 women worldwide every year.

"The launch of our new HPV product is a very important step in the field of women's health," stated Heino von Prondzynski, Head of Roche Diagnostics and Member of the Roche Executive Committee. "Significant progress has been made during the last few decades in detecting cervical abnormalities through regular screening with Pap tests. However, Pap tests often produce inconclusive or equivocal results, leading to a large unmet medical need to enhance the diagnosis of pre-cancerous cervical abnormalities through the use of an HPV PCR test. Through the approval of reimbursement initiatives for HPV screening, governments around the world are now recognizing the importance of HPV screening in preventing cervical cancer."

During the last decade, Roche has provided linear array research reagents for HPV to dozens of leading cancer investigators worldwide. This assistance to the world research community has been invaluable in characterizing the epidemiology and identification of HPV genotypes associated with cervical cancer. Research findings on HPV and cervical cancer conducted with the aid of Roche's

HPV linear arrays have been published in many leading peer-reviewed journals. At the upcoming International Human Papillomavirus Conference in Mexico City in February, numerous abstracts will be presented with data on the performance and potential clinical application of the new Roche PCR HPV tests, which include microwell plate and linear array formats.

Besides the Amplicor HPV product, Roche Diagnostics is also developing a PCR-based linear array test that identifies 37 HPV genotypes, including the most common high- and low-risk anogenital genotypes. This assay, based on a proven format used by more than 30 laboratories worldwide, is positioned to serve as a follow-up on positive results, to confirm positives, and to offer genotype information that will assist physicians with choosing the next steps on treatment. Also in development is an HPV test for use on the Cobas TaqMan Analyzer, which will couple HPV detection with Roche's real-time PCR technology in a simple, automated real-time platform.

About Cervical Cancer and HPV

According to the World Health Organization, cervical cancer is the second biggest cause of female cancer mortality worldwide with close to 300,000 deaths yearly. In the absence of screening programs (routine Pap smear), cervical cancer is detected too late and leads to death in almost all cases. Almost all (99.8%) cervical cancers are caused by specific types of a sexually-transmitted DNA tumor virus called human papillomavirus (HPV).

About Cervical Cancer Screening in the US

To screen for cervical cancer, 160 million Pap tests are performed each year worldwide, 50 to 60 million in the US alone. The PAP test alone is only 80 percent effective in detecting the precursors of cervical cancer. Furthermore, "inconclusive" Pap tests – where very mild abnormalities are identified and the presence of a cervical precancer is unclear – occur in about 3 to 5 percent of all Pap tests. The American College of Obstetricians and Gynecologists, the American Cancer Society and the Association of Reproductive Health Professionals have updated their screening guidelines to include HPV DNA testing as part of routine cervical cancer screening for women age 30 and older.

About Roche's PCR technology

Roche's patented polymerase chain reaction (PCR) technology is one of the most advanced methods in molecular diagnostics and one that carned its discoverer a Nobel Prize in Chemistry in 1993. PCR allows minute amounts of genetic material to be amplified into billions of copies (that is, to detectable levels) in only a few hours. In addition to its applications in nucleic acid fingerprinting and the diagnosis and monitoring of disease, PCR enables detection of infectious agents early in the infection cycle, often before symptoms appear. Standard immunoassay testing, by contrast, detects evidence of the body's immune response (antibodies) later in the infection cycle, leaving an

increased period during which infections can be missed. Through its global licensing and scientific collaboration programs Roche has developed and encouraged the utility of PCR technology for a wide variety of clinical and research applications.

About Roche and Roche Diagnostics

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Additional information

- Roche Diagnostics: www.roche-diagnostics.com
- Polymerase Chain Reaction (PCR): www.roche.com/pages/facets/pcr_e.pdf
- World Health Organization (WHO) & cancer: www.who.int/cancer/en/

Media Release

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Basel, 29 January 2004

Roche's oral flu drug Tamiflu could be effective in treating avian influenza

Roche confirms today that Tamiflu (oseltamivir) could be effective in treating the recent outbreak of the avian influenza in the Far East. Tamiflu was tested in a pre-clinical setting against a wide range of influenza virus strains. Despite the lack of clinical data, the findings provide reassurance that Tamiflu can be expected to be active against any influenza virus neuraminidase enzyme subtype, including the H5N1 strain. This strain is associated with the recent outbreak of avian influenza in Asia.

The WHO in its interim recommendations for the protection of persons in contact with animals potentially infected with highly pathogenic avian influenza viruses, advises that 'Oseltamivir be readily available for the treatment of suspected H5N1 respiratory infections in cullers and farm workers involved in the mass culling'.

"Roche is committed to making Tamiflu available to fight this latest avian influenza outbreak. Based on the current WHO approach we have adequate supplies and we continue to work closely with the authorities and our affiliates worldwide in order to monitor the development and act accordingly" says William M. Burns, Head of Roche Pharmaceuticals Division.

About avian influenza

According to the WHO avian influenza is an infectious disease of birds caused by type A strains of the influenza virus. Fifteen subtypes of influenza virus are known to infect birds, thus providing an extensive reservoir of influenza viruses potentially circulating in bird populations. To date, all outbreaks of the highly pathogenic form have been caused by influenza A viruses of subtypes H5 and H7.

About Tamiflu

Tamiflu, co-developed with Gilead Sciences is a systemic drug for all common strains of influenza (types A and B). The medication targets one of two major surface structures on the influenza virus, the neuraminidase protein. The neuraminidase protein is virtually the same in all common strains of influenza. If neuraminidase is inhibited, the virus is not able to infect new cells.

Treatment studies in adults show that Tamiflu provides a significant reduction in the severity of symptoms over and above symptom relievers alone, allowing people to feel better faster and to return to their normal lives more quickly. In children Tamiflu, taken orally as a convenient sirup also reduced severity of symptoms and reduced the occurrence of otitis media, a secondary infection often seen with influence disease. Tamiflu has been shown to be effective in a variety of settings for the prevention of influenza, providing immediate protection during an influenza outbreak.

Tamiflu is approved for the treatment of influenza in over 50 countries world-wide including Australia, Canada, EU, Japan, Switzerland. United States, as well as many countries in the Far East and Latin America. More than 10 million patients have been treated with Tamiflu since launch. It is also approved in many countries for the prevention of influenza in adolescents and adults and for the treatment of influenza in children aged 1 year and above.

The influenza virus responsible for the outbreak in Hong Kong in 1997 was also an 'H5N1' strain and Tamiflu demonstrated activity in an animal model at concentrations equivalent to those of the 75 mg twice daily dose approved for treating influenza in humans.

About Roche

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About Gilead

Gilead Sciences, Inc., headquartered in Foster City, CA, USA, is an independent biopharmaceutical company that seeks to provide accelerated solutions for patients and the people who care for them. Gilead discovers, develops, manufactures and commercialises proprietary therapeutics for challenging infectious diseases (viral, fungal and bacterial infections) and cancer. Gilead maintains research, development or manufacturing facilities in Foster City, CA; Boulder, CO; San Dimas, CA; Cambridge, UK; and Dublin, Ireland and sales and marketing organizations in United States, Europe and Australia.

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Further information:

www.health-kiosk.ch www.who.int www.cdc.gov

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WHO interim recommendations for the protection of persons involved in the mass slaughter of animals potentially infected with highly pathogenic avian influenza viruses. (WHO Regional Office for the Western Pacific, Manila, January 2004)